

## REMARKS

### I. Amendments

By this amendment, claims 1, 6, 13-15, 17, 18, 21 and 22 have been amended and claims 10-12 have been canceled.

This amendment adds no new matter to the specification. Support for this amendment is found in the specification and claims as filed.

No change of inventorship is necessitated by this amendment.

### II. Discussion of the Restriction Requirement

Claims 1-23 have been subjected to a restriction requirement. Applicants have previously elected a single species for examination. In the following paragraphs, the fact that the elected species is indeed within the scope of the claims and the conformance of the pending claims with the restriction requirement are discussed.

#### A. The Elected Species is Within the Scope of the Claims

The Examiner has concluded that the elected species does not fit into any of the claims, with reference to R<sup>1</sup>. However, this conclusion is incorrect. The elected species can be found within the scope of claim 1 by the following logic:

- 1) In claim 1, one of the possibilities for R<sup>1</sup> is an acyl group. In the specification, acyl groups are defined at page 34, line 3- page 40, line 14 and page 44, line 22 – page 45, line 1.

- 2)  $-\text{COR}^3$  is one of the choices for appropriate acyl groups for  $\text{R}^1$  as indicated on page 5, line 3.
- 3)  $\text{R}^3$  may be an optionally substituted aryl group, as indicated on page 34, line 23.
- 4) Optional substituents for the aryl group  $\text{R}^3$  include optionally substituted aryl groups, as indicated on page 30, line 12, with reference to page 34, line 24 – page 35, line 7.

In other words, if  $\text{R}^1$  is acyl, wherein acyl is  $-\text{COR}^3$  and  $\text{R}^3$  is an optionally substituted aryl group, wherein  $\text{R}^3$  is benzene substituted with benzene, the elected species is indeed found in the pending claims.

*B. The Pending Claims are in Accordance With the Restriction Requirement*

In order to advance prosecution, Applicants have amended their claims in accordance with the elected species, and with a view to provide a structure having a fixed backbone which the Examiner can readily search. To this end, Applicants have narrowed the definitions of ring A, ring B, D, E, G and X in independent claims 1, 14, 18, 21 and 22; and in dependent claims 6, and 15. These limitations add no new matter to the specification, as will be demonstrated in the following paragraphs.

By this amendment, ring A has been limited to “an optionally substituted homocyclic aromatic ring” in accordance with page 14, line 20 of the specification.

By this amendment, ring B has been limited to “an optionally-substituted benzene or cycloalkane ring”, in accordance with page 21, lines 7-8.

By this amendment, D has been limited to “an optionally substituted C<sub>1-6</sub> alkylene group” in accordance with page 26, line 6- page 27, line 12.

Also by this amendment, E has been limited to –CO(R<sup>a</sup>)-, “wherein R<sup>a</sup> represents a hydrogen atom or an optionally substituted C<sub>1-6</sub> alkyl group” in accordance with page 48, lines 11-21.

Additionally by this amendment, G has been limited to “an optionally substituted C<sub>1-6</sub> alkylene group” as disclosed in claim 14 *inter alia*.

Claims 2-5, 7, 9, 13 and 17 depend upon claim 1; while claims 8, 10-12, 16, 19, 20 and 23 have been cancelled. The more specific dependent claims are also in conformance with restriction requirement. Therefore, Applicants assert that the aspects of their invention as set forth in the pending claims as amended are appropriately limited, as described above.

For these reasons, Applicants respectfully submit that they have complied with the restriction requirement.

### **III. Discussion of the Rejection of Claims 1-23 under 35 U.S.C. Sec. 112, First Paragraph**

Claims 1-7, 9-11, 14, 15, 17, 18, 21 and 22 have been rejected under 35 U.S.C. Sec. 112, first paragraph as allegedly non-enabled with respect to R<sup>2</sup> when bonded to ring B a second time to form a bicyclic ring structure.

By this amendment, the option for R<sup>2</sup> to bond additionally to ring B to form a bicyclic ring structure has been removed from independent claims 1, 18, 21 and 22. In addition,

dependent claims 13 and 17 have also been modified to remove this option from the pending claims.

Newly independent claim 14 does not include the limitation at issue.

Claims 10 and 11 have been cancelled, and claims 2-7, 9 and 15 are dependent upon claim 1. Applicants submit that the more specific dependent claims are enabled for the same reason that claim 1 as amended is enabled, as argued above.

Therefore, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, first paragraph rejection.

#### **IV. Discussion of the Rejection of Claim 21 under 35 U.S.C. Sec. 112, First Paragraph**

Claim 21 has been rejected under 35 U.S.C. Sec. 112, first paragraph as allegedly lacking enablement. Applicants respectfully traverse this rejection, and provide detailed comments to address each of the Examiner's objections below.

##### **A. Prevention is No Longer Claimed**

Firstly, the Examiner's comments maintain that the claim is not enabled for the method of preventing certain conditions. By the previous amendment dated December 12, 2002, "preventing" was deleted from claim 21. Therefore, continued reference to the claim as not being enabled for this reason (as on page 3, second paragraph of the Office Action) is inappropriate.

B. The Claimed Conditions are Related

Secondly, the Examiner has indicated that the claim lacks enablement because it refers to treating various diseases, which the Examiner has assumed are unrelated. In response, Applicants wish to point out that many issued patents recite methods for treating this group of conditions together in one claim, indicating that it may not be correct to assume they are unrelated. U.S. Patent Nos. 6,352,982; 6,506,762; 6,515,117; 6,531,478 and 6,555,519 are just some of the many examples which should be considered, wherein the conditions of diabetes, obesity, complications of diabetes, or intractable diarrhea are all claimed together.

Those skilled in the art understand that compounds which regulate somatostatin can be useful for the treatment of several different conditions. A further example is provided by U.S. Patent No. 6,329,389; wherein it is taught that compounds which influence somatostatin receptor binding can be useful for treating diabetes and associated conditions (item (2) in col. 49); obesity (item (3) in col. 49) and diarrhea (item (7) in col. 49).

Applicants contend that the Examiner's statement that "claim 21 is still referring to the method of treating various diseases, many of which are unrelated" as found on page 6 of the Office Action is incorrect for the reasons provided above.

C. The Specification Provides Adequate Teaching

Applicants' specification describes the relationship of somatostatin receptor function to the treatment of various conditions at page 92, line 2 – page 97, line 21 *inter alia*. How the compounds can be formulated and administered is addressed on page 97, line 22 – page 102, line 24 *inter alia*. Therefore, the specification provides adequate guidance for those skilled in the art on how to carry out the presently claimed method.

Furthermore, it is Applicants' position that given the state of the art (as indicated by the example patents enumerated in Sec. IV B above) and the teachings of the specification, the experimental proof indicating somatostatin binding inhibition (Example 2 starting on page 423 of the specification) is sufficient to enable the method for treating each of the conditions recited in claim 21.

Since the Applicants have shown that there is good evidence that the conditions of claim 21 are not unrelated; and that the provided experimental evidence would be sufficient for one skilled in the art to understand how to treat the indicated conditions, Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, first paragraph rejection of claim 21.

**V. Discussion of the Rejection of Claim 22 under 35 U.S.C. Sec. 112, First Paragraph**

The Examiner has maintained the rejection of claim 22 under 35 U.S.C. Sec. 112, first paragraph as allegedly lacking utility.

By this amendment, Applicants have amended claim 22 to recite a method for agonizing somatostatin receptor function. This amendment adds no new matter to the specification. Support for the amendment may be found at page 92, lines 19-22 *inter alia*.

Applicants note that U.S. Patents which recite methods for agonizing various receptors have been issued. U.S. Patent Nos. 6,545,026; 6,500,934; 6,075,040 and 5,789,402 are among the examples of such patents. Therefore, Applicants assert that the aspect of their invention as set forth in claim 22 as amended does have utility.

Applicants respectfully request withdrawal of the 35 U.S.C. Sec. 112, first paragraph rejection of claim 22.

**VI. *Second Request for Consideration of a Previously Submitted Information Disclosure Statement***

This is a repeat of a request which had previously been made in Applicants' communication dated December 12, 2002. Applicants urge the Examiner to address this outstanding issue in the prosecution of their patent application.

Applicants filed an Information Disclosure Statement, Form 1449 and four cited references on April 6, 2001, but they have not received initialled PTO-1449 forms indicating the Examiner's review of the disclosed documents.

Applicants respectfully request the Examiner's consideration of the previously submitted references. If the 1449 or copies of any of the references are missing from the Examiner's file, replacements may be obtained from Applicants' Attorney.

**VII. Conclusion**

Reconsideration of the claims as amended and allowance is requested. Should the Examiner believe that a conference with Applicants' attorney would advance prosecution of this application, the Examiner is respectfully requested to call Applicants' attorney at (847) 383-3391.

Respectfully submitted,

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